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Co-production and evaluation of an e-learning resource to improve African Caribbean families' knowledge about schizophrenia and engagement with services

Submission date
19/03/2018

Recruitment status
No longer recruiting

Registration date
20/03/2018

Overall study status
Completed

Last Edited
29/11/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Schizophrenia is a severe long-term mental health condition where the person may not always be able to distinguish their own thoughts and ideas from reality. Improving family members' attitudes and knowledge about schizophrenia has been shown to reduce family tensions and hostility and create more sympathetic home environments, which in turn reduces the risk of relapse and rehospitalisation. Stigmatising attitudes towards persons with mental illness in the wider community have been reported to negatively affect service users' outcomes. NICE guidance suggests family-focused interventions for African Caribbean families with schizophrenia are urgently needed. As there are currently no culturally-appropriate, psychological education resources for this group, the aim of this study is to work with families and service users to develop and test such a resource in this ethnic group.

Who can participate?
People aged 16 and over with a relative of Black Caribbean heritage (including 'Black British' and 'Mixed' heritage) with schizophrenia or other non-affective psychosis

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the treatment group complete assessments of their knowledge about psychosis, attitudes towards mental illness and their subjective health. They are then given access to the e-learning resource, and asked to explore the resource on their pace with no minimum requirements for how often or how much at once they should use the resource. After 2 weeks, participants are asked to complete the same assessments and attend an interview. Finally, participants are invited to complete the assessments after 3 months. Participants in the control group are also tested at the same times but do not receive the intervention until after data collection has ended.

What are the possible benefits and risks of participating?
The researchers cannot promise that the study will help the participants directly but they are

doing this research because they believe that the programme will help to improve care and support for African Caribbean patients with schizophrenia and their families. They believe that improving carers and families' knowledge and awareness of schizophrenia and understanding of health professional roles will improve relationships within families. Collecting information on knowledge about schizophrenia/other psychoses and quality of life will enable them to choose the best ways of measuring the impact of the programme in future studies. Ultimately, they hope that this programme will reduce family stress and tension, which should improve outcomes for patients. Thinking and learning more about mental illness and mental health services might be upsetting for some people. Participants can stop at any point if they feel upset. If they feel distressed whilst using the programme they can contact the lead researcher, Dr Dawn Edge, at the University on 0161 275 2570. The researchers also provide a list of organisations that are able to provide support to all participants and help them to get support if they wish.

Where is the study run from?
1. The University of Manchester (UK)
2. Manchester Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
May 2015 to August 2018

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Dawn Edge

Contact information

Type(s)
Scientific

Contact name
Dr Dawn Edge

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Contact details
Coupland 1 building
The University of Manchester
Oxford Road
Manchester
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M13 9PL

Additional identifiers

Protocol serial number
37800

Study information

Scientific Title
Co-production and evaluation of an e-learning resource to improve African Caribbean families' knowledge about schizophrenia and engagement with services

Acronym
Casper

Study objectives
Improving family members' attitudes and knowledge about schizophrenia has been shown to reduce family tensions and hostility thus creating more sympathetic home environments, which in turn reduces risk of relapse and rehospitalisation. Stigmatising attitudes towards persons with mental illness in the wider community has been reported to negatively affect service users' outcomes. NICE guidance suggests family-focused interventions for African Caribbean families with schizophrenia are urgently needed. As there are currently no culturally-appropriate, psychological education resources for this group, we plan to work with families and service users to develop and test such a resource in this ethnic group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City & East Research Ethics Committee, 03/06/2015, ref: 15/LO/0896

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental health, Primary sub-specialty: Psychosis - schizophrenia; UKCRC code/ Disease: Mental Health/ Schizophrenia, schizotypal and delusional disorders

Interventions
Participants are randomised using sealedenvelope.com.

Participants in the treatment group will complete baseline measures assessing their knowledge about psychosis, attitudes towards mental illness and their subjective health. After the baseline data collection, participants will be given access to the e-learning resource, and asked to explore the resource on their pace with no minimum requirements for how often or how much at once they should use the resource. After 2 weeks (duration of treatment) of gaining access to the resource, participants will be asked to complete the same measures and attend an interview. Finally, participants will be invited to complete the measures after 3 months (follow up time).

The control group will also be tested at the same timepoints but will not receive the intervention until after research data collection has ended.

Intervention Type
Other

Primary outcome(s)
1. Knowledge about psychosis is measured using the Culturally-Adapted Knowledge About Psychosis Questionnaire at baseline, 2 weeks and 3 months
2. Attitudes towards mental illness are measured with the Anxiety Surrounding Mental Illness Scale at baseline, 2 weeks and 3 months

Key secondary outcome(s))
1. Acceptability of the intervention is measured with an interview comprising questions about participants' experiences of using the intervention
2. Participants' health is measured with the SF-12 Health Survey v2 at baseline, 2 weeks and 3 months

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Must have a relative of Black Caribbean heritage (including 'Black British' and 'Mixed' heritage) with a diagnosis of schizophrenia or other non-affective psychosis
2. Minimum age 16, no upper age limit
3. Sufficient English skills to access the intervention and complete the measures

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Persons without a relative of Black Caribbean heritage with a schizophrenia/non-affective psychosis diagnosis
2. Health professionals
3. Under 16s

Date of first enrolment
01/09/2017

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Manchester
Jean McFarlane building
Oxford Road
Manchester
United Kingdom
M13 9PL

Study participating centre
Greater Manchester Clinical Research Network
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
The University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG- 0212-27109

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/11/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V3	14/09/2017	20/03/2018	No	Yes
Protocol file	version V3	14/09/2017	20/03/2018	No	No